Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area. Page # 1 of 2 Row 1 Reporter name: Submission Contact person (if different than reporter) Internal ID date: Administrative Gordon Sargent 10/15/2020 Data Address: Address: Nufarm Americas Inc 4020 Aerial Center Parkway Morrisville, NC 27560 Phone #: Phone #: (919) 379-2529 Incident Status: Location and date of incident Date registrant Was incident part of larger study? became aware of No New Study report received incident: 10/14/2020 10/14/2020 Row 2 EPA Registration # (Product 1) EPA Registration # (Product 2) EPA Registration # (Product 3) 35935-48 Pesticide(s) Involved A.I. (s) A.I. (s) A.I. (s) Lambda-cyhalothrin Product 1 Name Product 2 Name Product 3 Name Lambda-cyhalothrin Technical Exposed to concentrate prior to Exposed to concentrate prior to Exposed to concentrate prior to dilution? NA dilution? dilution? Formulation Formulation Formulation Row 3 Evidence label Incident site: (examples include home, yard, Situation: (act of using product): directions were not school, industrial, nursery/greenhouse, (examples include mixing/loading, Incident followed? NA surface water, commercial turf, reentry, application, transportation, repair/ Circumstances Intentional misuse? NA building/office, forest/ woods, agricultural maintenance of application equipment, (specify crop) right-of-way (rail, utility, manufacturing/ formulating) highway)) Applicator certified Seed description notes PCO? NA Performing Laboratory: **BIOAGRI Laboratorios** How exposed: Fazenda Lagoa Bonita, Chacara 13 (examples include Caixa Postal 08287 - Plnaltina DF 73310direct contact with 970 BRAZIL treated surface, ingestion, spill, drift, runoff) Acute Inhalation Toxicity Test of Lambda-cyhalothrin Tecnico Agripec in Rats

Voluntary Industry Reporting Form for 6(a)(2) Incident Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area. Page # 3 of 2

Demographic information Age: Sex: Occupation: (if relevant)	Exposure route: Inhalation	Was adverse effect result of suicide/homicide or attempted suicide/homicide? NA	Was protective clothing worn (specify)? NA
If female, pregnant? NA	Was exposure occupational? No If yes, days lost due to illness:	Time between exposure and onset of symptoms: See study report	
Type of medical care sought: (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient). <i>NA</i>	List signs/symptoms/adverse effe	ects.	If lab tests were performed, list test names and results (If available, submit reports). Acute Inhalation Toxicity Test of Lambda-cyhalothrin Tecnico Agripec in Rats
Exposure data: Amount of pesticide: Exposure duration: Weight: See study report Human severity category: NA			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Study Title: Acute Inhalation Toxicity Test of Lambda-cyhalothrin Tecnico Agripec in Rats

Study Concluded on: 02/07/2007

Performing Laboratory: BIOAGRI Laboratorios

Sponsor: AGRIPEC QUIMICA E FARMACEUTICA

Summary:

"The acute inhalation toxicity test in rats (Rattus norvegicus, Wistar-Hannover) was carried out in order to study the possible toxic effects observed after airborne exposure to LAMBDA CYHALOTHRIN TECNICO AGRIPEC, according to the OECD Guideline 403, 1981.

Three groups of rats (five/sex/concentration) were nose-only exposed to the test item aerosolized diluted in dimethylsulphoxide (DMSO) for a 4-hour exposure period, using a total airflow of 8 L/min. The control group was similarly exposed to DMSO. The aerodynamic particle-size distribution indicated that 41.56 to 52.15% of the aerosol generated was within the respirable size range, with a Mass Median Aerodynamic Diameter (MMAD) from 3.470 to 4.018 μ m, and a Geometric Standard Deviation (GSD) from 1.687 to 1.906. The mean actual concentrations tested were 0.013, 0.039 and 0.125 mg/L.

Death was recorded after exposure to the mean actual concentrations of 0.039 mg/L (6 or 20%) and 0.125 mg/L (10 or 33.33%)...

...Therefore, the combined (male and female) median lethal concentration in a 4-hour nose-only exposure period (4-h LC50) to LAMBDA CYHALOTHRIN TECNICO AGRJPEC inhaled by Wistar-f!annover rats was estimated as 0.04 mg/L, with a 95% confidence interval from 0.03 to 0.05 mg/L."

Internal ID #	

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area. Page # 1 of 2 Row 1 Reporter name: Submission Contact person (if different than reporter) Internal ID date: 10/27/2020 Administrative Gordon Sargent (resubmission) Data Address: Address: Nufarm Americas Inc 4020 Aerial Center Parkway Morrisville, NC 27560 Phone #: Phone #: (919) 379-2529 Location and date of incident Incident Status: Date registrant Was incident part of larger study? became aware of No New Study report received incident: 10/14/2020 10/14/2020 Row 2 EPA Registration # (Product 1) EPA Registration # (Product 2) EPA Registration # (Product 3) 35935-48 Pesticide(s) Involved A.I. (s) A.I. (s) A.I. (s) Lambda-cyhalothrin Product 1 Name Product 2 Name Product 3 Name Lambda-cyhalothrin Technical Exposed to concentrate prior to Exposed to concentrate prior to Exposed to concentrate prior to dilution? NA dilution? dilution? Formulation Formulation Formulation Row 3 Evidence label Incident site: (examples include home, yard, Situation: (act of using product): directions were not school, industrial, nursery/greenhouse, (examples include mixing/loading, Incident followed? NA surface water, commercial turf, reentry, application, transportation, repair/ Circumstances Intentional misuse? NA building/office, forest/ woods, agricultural maintenance of application equipment, (specify crop) right-of-way (rail, utility, manufacturing/ formulating) highway)) Applicator certified Seed description notes PCO? NA Performing Laboratory: **BIOAGRI Laboratorios** How exposed: Fazenda Lagoa Bonita, Chacara 13 (examples include Caixa Postal 08287 - Plnaltina DF 73310direct contact with 970 BRAZIL treated surface, ingestion, spill, drift, runoff) Acute Inhalation Toxicity Test of Lambda-cyhalothrin Tecnico Agripec in Rats

Voluntary Industry Reporting Form for 6(a)(2) Incident Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area. Page # 3 of 2

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Exposure data: Amount of pesticide: Exposure duration: Weight: See study report Human severity category: NA			

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Death was recorded after exposure to the mean actual concentrations of 0.039 mg/L (6 or 20%) and 0.125 mg/L (10 or 33.33%)...

...Therefore, the combined (male and female) median lethal concentration in a 4-hour nose-only exposure period (4-h LC50) to LAMBDA CYHALOTHRIN TECNICO AGRJPEC inhaled by Wistar-f!annover rats was estimated as 0.04 mg/L, with a 95% confidence interval from 0.03 to 0.05 mg/L."

Internal ID #	





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DATA MATRIX					
Date August 10, 2020	EPA Reg. No./File Symbol 35935-48 Page 1 of 15				
Nufarm Limited 4020 Aerial Center Parkway Morrisville, NC 27560	Product: Lambda-cyhalothrin Technical (NFA-0480001)				
Ingredient: Lambda-cyhalothrin (PC Code 128897)					

Guideline Reference Series Name MRID Number Submitter (EPA CO#) Status Note Number **SERIES 810** PRODUCT PERFORMANCE TEST GUIDELINES 43858601 100 PER 810.3100 TGAI – General Consideration for Efficacy 44191401 100 PER 48762913 PER 64977 **SERIES 830** PRODUCT PROPERTIES TEST GUIDELINES TGAI - Product Identity and Composition NUFARM OWN 830.1550 51192701 51192701 830.1600 TGAI - Description of the Materials Used to Produce the Product NUFARM OWN 51192701 **NUFARM** 830.1650 TGAI - Description of the Production Process OWN 51192701 830.1670 TGAI - Discussion of Formation of Impurities NUFARM OWN 51192701 TGAI - Preliminary Analysis **NUFARM** 830.1700 OWN 51192701 830.1750 TGAI - Certified Limits NUFARM OWN 51192701 NUFARM 830.1800 TGAI - Enforcement Analytical Method OWN 51192702 NUFARM OWN TGAI - Color 830.6302 51192702 NUFARM OWN 830.6303 TGAI - Physical State 51192702 NUFARM OWN TGAI - Odor 830.6304 51192702 830.6313 TGAI - Stability to normal / elevated temperatures, metals and metal ions NUFARM OWN 51192702 830.6314 TGAI - Oxidizing/Reducing Reaction NUFARM OWN 51192702 830.6315 TGAI - Flammability NUFARM OWN 51192702 830.6316 TGAI - Explodability **NUFARM** OWN

Signature /	()	Name and Title:	Date
(y	Carrie M. Tackema, Sr. Regulatory Manager	8-10-20





DATA MATRIX					
Date August 10, 2020	EPA Reg. No./File Symbol 35935-48	Page 2 of 15			
Nufarm Limited 4020 Aerial Center Parkway Morrisville, NC 27560	Product: Lambda-cyhalothrin Technical (NFA-0480001)	_			
Ingredient: Lambda-cyhalothrin (PC Code 128897)					

Guideline Reference Number	Series Name	MRID Number	Submitter (EPA CO#)	Status	Note
SERIES 830	PRODUCT PROPERTIES TEST GUIDELINES				
830.6317	TGAI - Storage Stability	51192702	NUFARM	OWN	
830.6319	TGAI - Miscibility				not required
830.6320	TGAI - Corrosion Characteristics	51192702	NUFARM	OWN	
830.6321	TGAI - Dielectric Breakdown Voltage				not required
830.7000	TGAI - pH	51192702	NUFARM	OWN	
830.7050	TGAI - UV/Visible Absorption				not required
830.7100	TGAI - Viscosity				not required
830.7200	TGAI - Melting Point	51192702	NUFARM	OWN	
830.7220	TGAI - Boiling Point/Boiling Range	51192702	NUFARM	OWN	
830.7300	TGAI - Density, Bulk Density, Specific Gravity	51192702	NUFARM	OWN	
830.7370	TGAI - Dissociation Constant	51192702	NUFARM	OWN	
830.7550 830.7560 830.7570	TGAI - Partition Coefficient (n-octanol/water)	51192702	NUFARM	OWN	
830.7840 830.7860	TGAI - Water Solubility	51192702	NUFARM	OWN	
830.7950	TGAI - Vapor Pressure	51192702	NUFARM	OWN	

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	(SP		Carrie M. Tackema, Sr. Regulatory Manager	8-10-20





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DATA MATRIX

Date August 10, 2020 EPA Reg. No./File Symbol 35935-48 Page 3 of 15

Nufarm Limited
4020 Aerial Center Parkway
Morrisville, NC 27560
Product: Lambda-cyhalothrin Technical (NFA-0480001)

Ingredient: Lambda-cyhalothrin (PC Code 128897)

Guideline Reference Number	Series Name	MRID Number	Submitter (EPA CO#)	Status	Note
SERIES 835	FATE, TRANSPORT AND TRANSFORMATION TEST GUIDELINES				
835.1230	TGAI – Adsorption/Desorption	44861503 44861507 44861509 44074403 44074404 44074405 44074406 44074407 44075601	100 100 100 64977 64977 64977 64977 64977 64977	PER PER PER PER PER PER PER PER PER	
835.1240	TGAI – Leaching Studies	44075505 46535601 46535602 46535603 46535604 47647801 48072901 48762906 48762907 48762908	100 64977 64977 64977 64977 64977 64977 64977 64977	PER	
835.2120	TGAI- Hydrolysis				
835.2240	TGAI- Photodegradation in Water	44861501 44861506 44861508	100 100 100	PER PER PER	
835-2410	TGAI- Photodegradation in Soil				
835.4100	TGAI- Aerobic Soil Metabolism	44861504 44861505	100 100	PER PER	_
835.4200	TGAI- Anaerobic Soil Metabolism				

Signature /	TV	Name and Title:	Date
	3	Carrie M. Tackema, Sr. Regulatory Manager	8-10-20





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Date August 10, 2020 EPA Reg. No./File Symbol 35935-48 Page 4 of 15 Nufarm Limited 4020 Aerial Center Parkway Morrisville, NC 27560 Product: Lambda-cyhalothrin Technical (NFA-0480001)

Guideline Reference Number	Series Name	MRID Number	Submitter (EPA CO#)	Status	Note
SERIES 835	FATE, TRANSPORT AND TRANSFORMATION TEST GUIDELINES				
835.4300	TGAI- Aerobic Aquatic Metabolism	44075504 44367401	100 100	PER PER	
835.4400	TGAI – Anaerobic Aquatic Metabolism	44075504	100	PER	
835.6100	TGAI - Terrestrial Field Dissipation				
835.6200	TGAI – Aquatic (sediment) field dissipation	44075504 44367403 44367404 44367404	100 100 100	PER PER PER	
SERIES 840	SPRAY DRIFT TEST GUIDELINES				
840.1000	Background for Pesticide Aerial Drift Evaluation	42976801	64977	PER	
840.1100	Spray Droplet Size Spectrum				
840.1200	Spray Drift Field Deposition				
SERIES 850	ECOLOGICAL EFFECTS TEST GUIDELINES				
850.1010	TGAI – Aquatic Invertebrate Acute Toxicity Freshwater Daphnids	44584001 43908810 44074401 44074402	100 100 64977 64977	PER PER PER PER	
850.1025	TGAI – Oyster Acute Toxicity				
850.1035	TGAI- Mysid Acute Toxicity				
850.1045	TGAI – Penaeid Acute Toxicity				
850.1055	TGAI – Bivalve Acute Toxicity				
850.1075	TGAI- Freshwater and Saltwater Fish Acute Toxicity				

Signature

Name and Title:
Carrie M. Tackema, Sr. Regulatory Manager

8-10-20

Ingredient: Lambda-cyhalothrin (PC Code 128897)





DATA MATRIX					
Date August 10, 2020		EPA Reg. No./File Symbol 35935-48	Page 5 of 15		
Nufarm Limited 4020 Aerial Center Parkway Morrisville, NC 27560		Product: Lambda-cyhalothrin Technical (NFA-0480001)			
Ingredient: Lambda-cyhalothrin (PC	C Code 128897)				

Guideline Reference Number	Series Name	MRID Number	Submitter (EPA CO#)	Status	Note
SERIES 850	ECOLOGICAL EFFECTS TEST GUIDELINES				
850.1300	TGAI – Daphnid Chronic Toxicity				
850.1400	TGAI- Fish Early Life Stage Toxicity				
850.1500	TGAI- Fish Full Life-Cycle Toxicity				
850.1735	TGAI – Spiked Whole Sediment 10-day Toxicity Test, Freshwater Invertebrates	46725701 47946601 47946602 47946603 47946604 47946605 48593616 48593601 485936002 48593606 48593607 48593605 48593605 48593601 48593611 48528302 48593611 48528302 48593613 48593614 48593615 48593617 48593617 48593603 48593604 49016601 49035801	64977 64977	PER	

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Signature	D		Name and Title: Carrie M. Tackema, Sr. Regulatory Manager	Date 8-10-20





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DATA MATRIX Date August 10, 2020 EPA Reg. No./File Symbol 35935-48 Page 6 of 15 Nufarm Limited 4020 Aerial Center Parkway Morrisville, NC 27560 Product: Lambda-cyhalothrin Technical (NFA-0480001)

Ingredient: Lambda-cyhalothrin (PC Code 128897)

Guideline Reference Number	Series Name	MRID Number	Submitter (EPA CO#)	Status	Note
SERIES 850	ECOLOGICAL EFFECTS TEST GUIDELINES				
850.1740	TGAI – Spiked Whole Sediment 10-day Toxicity Test, Saltwater Invertebrates	46591501 46591502 46591503 46591504 46591505 46591506 46591507 46620401	64977 64977 64977 64977 64977 64977 64977 64977	PER PER PER PER PER PER PER	
850.1790	TGAI – Sediment Toxicity Testing	46871501 48762901 48762902 48762903 48762904 48762905 48857501 48857502 48857503 48857504 48857504	64977 64977 64977 64977 64977 64977 64977 64977 64977 64977	PER	
850.2100	TGAI- Avian Acute Oral Toxicity				
850.2200	TGAI- Avian Dietary Toxicity				
850.2300	TGAI- Avian Reproduction				
850.3020	TGAI- Honey Bee Acute Contact Toxicity				
850.4100	TGAI- Seedling Emergence and Seedling Growth				
850.4150	TGAI- Vegetative Vigor				
850.4400	TGAI- Aquatic Plant Growth				
850.5400	TGAI – Aquatic Plant Toxicity (Lemna spp.)				

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Signature /	TV	Name and Title:	Date
(Y	Carrie M. Tackema, Sr. Regulatory Manager	8-10-20





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DATA MATRIX					
Date August 10, 2020	EPA Reg. No./File Symbol 35935-48	Page 7 of 15			
Nufarm Limited					
4020 Aerial Center Parkway	Product: Lambda-cyhalothrin Technical (NFA-0480001)				
Morrisville, NC 27560	Troduct. Lambaa synaisanin resinnean (11174 5455551)				

Ingredient: Lambda-cyhalothrin (PC Code 128897)

Guideline Reference Number	Series Name	MRID Number	Submitter (EPA CO#)	Status	Note
SERIES 860	RESIDUE CHEMISTRY TEST GUIDELINES				
860.1100	TGAI - Chemical Identity	45698201	100	PER	
860.1200	TGAI - Directions for Use	45114601	100	PER	
860.1300	TGAI - Nature of the Residue – Plants, Livestock				
860.1340	TGAI - Residue Analytical Method	47050501 47050502 47050502 47050503 47050504 47050505 47050506 47050507 47053001 47053002 47058601 47506602 47506603 48072902 48762909 48762910 48762916 48762917 48762915 47929406 48762911 48762911 48762911 48762911 48762911 48762911 48762911 48762911 48762911 48762911 48762911 48762911 48762911 48762911 48762910 48762911 48762910 48762910 48762910 48762910 48762910 48762910 48762910 48762920 4881301 48762920 48851301 48935001	64977 64977		
Guideline Reference Number	Series Name	MRID Number	Submitter (EPA CO#)	Status	Note

Signature

Name and Title:
Carrie M. Tackema, Sr. Regulatory Manager

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DATA MATRIX

Date August 10, 2020 EPA Reg. No./File Symbol 35935-48 Page 8 of 15

Nufarm Limited 4020 Aerial Center Parkway Morrisville, NC 27560 Product: Lambda-cyhalothrin Technical (NFA-0480001)

Ingredient: Lambda-cyhalothrin (PC Code 128897)

SERIES 860	RESIDUE CHEMISTRY TEST GUIDELINES				
860.1340	TGAI – Residue Analytical Method	45245501 46051301 46620402 46620403 46620404 46620405 46938301	64977 64977 64977 64977 64977 64977 64977	PER PER PER PER PER PER PER	
860.1360	TGAI - Multiresidue Method				
860.1380	TGAI - Storage Stability Data				
860.1500	TGAI - Crop Field Trials	45443100 45443101 45443102 45443103 45443104 45443105 45669201 46665301 46665302 46665303 46665303 46665304 46665305 43294701 43296301 43296301 43296302 43421701 43421702 43421702 43421703 43421704 43421705 43421706 43421707 43421708 43421708 43421709 43421709 43488001 43488001 43488002	100 100 100 100 100 100 100 100 100 100	PER R PER PE	

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Signature	V	MIN	Name and Title: Carrie M. Tackema, Sr. Regulatory Manager	Date 8-10-20





DATA MATRIX						
Date August 10, 2020	EPA Reg. No./File Symbol 35935-48	Page 9 of 15				
Nufarm Limited 4020 Aerial Center Parkway Morrisville, NC 27560	Product: Lambda-cyhalothrin Technical (NFA-0480001)					
Ingredient: Lambda-cyhalothrin (PC Code 128897)						

Guideline Reference Number	Series Name	MRID Number	Submitter (EPA CO#)	Status	Note
SERIES 860	RESIDUE CHEMISTRY TEST GUIDELINES				
860.1500	TGAI – Crop Field Trials	43781001 43781002 43781002 43781003 43908816 42761201 42761202 42761203 42761205 42761206 42919201 43032001 43908817 44075501 44075501 44075501 44325702 44325702 44325703 44325704 44325705 44325706 44325707 44325709 44325710 44325710 44325710 44325710 44325710 44325710 44325710 44325710 44325710 44325710 44325709 44325710 44325710 44325710 44325710 44325710 44325710 44325710 44325712 44820201 44820202 45007001 45007002	100 100 100 100 100 100 100 100 100 100	PER	

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Signature	D		Name and Title: Carrie M. Tackema, Sr. Regulatory Manager	Date 8-10-20





DATA MATRIX							
Date August 10, 2020	EPA Reg. No./File Symbol 35935-48	Page 10 of 15					
Nufarm Limited 4020 Aerial Center Parkway Morrisville, NC 27560 Product: Lambda-cyhalothrin Technical (NFA-0480001)							
Ingredient: Lambda-cyhalothrin (PC Code 128897)	ngredient: Lambda-cyhalothrin (PC Code 128897)						

Guideline Reference Number	Series Name	MRID Number	Submitter (EPA CO#)	Status	Note
SERIES 860	RESIDUE CHEMISTRY TEST GUIDELINES				
860.1500	TGAI – Crop Field Trials	45007004 45007006 45007007 45007008 45007009 45007012 45032401 45443101 45443103 45443104 45443105 45669201 46665302 46665302 46665303 46665304 46665305 40307101 40307103 41934601 41934603 41934604 42236001	100 100 100 100 100 100 100 100 100 100		
860.1550	TGAI - Proposed Tolerance				
860.1560	TGAI - Reasonable Grounds in Support of Petition	45007013 46686001	100 100	PER PER	
860.1650	TGAI - Submittal of Analytical Reference Standards				

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	(SP		Carrie M. Tackema, Sr. Regulatory Manager	8-10-20





	DATA MATRIX								
Date	Date August 10, 2020 EPA Reg. No./File Symbol 35935-48 Page 11 of 15								
4020 A	Limited erial Center Parkway rille, NC 27560	Product: Lambda-cyhalothrin Technical (NFA-0480001)							
Ingredie	Ingredient: Lambda-cyhalothrin (PC Code 128897)								

Guideline Reference Number	Series Name	MRID Number	Submitter (EPA CO#)	Status	Note
SERIES 870	HEALTH EFFECTS TEST GUIDELINES				
870.1100	TGAI- Acute Oral Toxicity (rat)	44353501 45698201	100 100	PER PER	
870.1200	TGAI- Acute Dermal Toxicity				
870.1300	TGAI- Acute Inhalation Toxicity				
870.2400	TGAI- Primary Eye Irritation				
870.2500	TGAI- Primary Skin Irritation				
870.2600	TGAI- Skin Sensitization				
870.3100	TGAI- 90-Day Oral Toxicity (rat)	43241901	100	PER	
870.3150	TGAI- 90-Day Oral Toxicity (non-rodent)				
870.3200	TGAI- 21/28-Day Dermal Toxicity	44353501	100	PER	
870.3700	TGAI- Prenatal Developmental Toxicity				
870.3800	TGAI- Reproduction and Fertility Effects				
870.4100	TGAI- Chronic Toxicity	43227901 43232101 43241902 43241903 43245301 4330801 43403401 43781004 44075503 44325711 44353503 44439501 45568001	100 100 100 100 100 100 100 100 100 100	PER	

	_			
Signature /	TV	1/ ^	Name and Title:	Date
_ (Y	\mathcal{M}	Carrie M. Tackema, Sr. Regulatory Manager	8-10-20





DATA MATRIX								
Date August 10, 2020	EPA Reg. No./File Symbol 35935-48	Page 12 of 15						
Nufarm Limited 4020 Aerial Center Parkway Morrisville, NC 27560	Product: Lambda-cyhalothrin Technical (NFA-0480001)							
Ingredient: Lambda-cyhalothrin (PC Code 128897)								

Guideline Reference Number	Series Name	MRID Number	Submitter (EPA CO#)	Status	Note
SERIES 870	HEALTH EFFECTS TEST GUIDELINES				
870.4200	TGAI- Carcinogenicity	43241902	100	PER	
870.5100	TGAI- Bacterial Reverse Mutation				
870.5300	TGAI- In Vitro Mammalian Gene Mutation				
870.5375	TGAI- In Vitro Mammalian Chromosome Aberration				
870.5385	TGAI – Mammalian Bone Marrow Chromosomal Aberration				
870.5395	TGAI – Mammalian Erythrocyte Micronucleus Test				
870.6200	TGAI – Neurotoxicity Screening Battery	44861510 45689101 45714301 45811001 45811002 45811003	100 100 100 100 100 100	PER PER PER PER PER PER	
870.6300	TGAI – Developmental Neurotoxicity Study	46449101 46449102 46526801 46526802 46526803 46526804 46526805	100 100 100 100 100 100 100	PER PER PER PER PER PER	
870.7485	TGA I- Metabolism and Pharmacokinetics	44333801	100	PER	
870.7800	TGAI - Immunotoxicity				
870 / 85-2	TGAI – Special studies – In Vivo Percutaneous Absorption Study (rat)	44990402	100	PER	

Signature /	D	Name and Title:	Date
_ (Y	Carrie M. Tackema, Sr. Regulatory Manager	8-10-20





Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX								
Date August 10, 2020	EPA Reg. No./File Symbol 35935-48	Page 13 of 15						
Nufarm Limited 4020 Aerial Center Parkway Morrisville, NC 27560	Product: Lambda-cyhalothrin Technical (NFA-0480001)							

Guideline Reference Series Name MRID Number Submitter (EPA CO#) **Status** Note Number **SERIES 875 OCCUPATIONAL AND RESIDENTIAL EXPOSURE TEST GUIDELINES OWN** 875.1100 TGAI - Dermal Exposure - Outdoor CITE ALL Footnote 1 CITE ALL OWN 875.1200 TGAI - Dermal Exposure - Indoor Footnote 1 CITE ALL OWN 875.1300 TGAI - Inhalation Exposure - Outdoor Footnote 1 CITE ALL **OWN** 875.1400 TGAI - Inhalation Exposure - Indoor Footnote 1 CITE ALL OWN 875.1600 TGAI – Application Exposure Monitoring Data Reporting Footnote 1 44964401 100 PER 875.2100 TGAI – Foliar Dislodgeable Residue Dissipation PER 44964402 100 44984401 100 PER PER 44984402 100 44990401 PER 100 PER 45007010 100 45269601 PER 100 43908815 100 PER 875.2200 TGAI – Soil Residue Dissipation PER 46844801 64977 CITE ALL **OWN** 875.2400 TGAI - Dermal Exposure Footnote 1 CITE ALL **OWN** 875.2500 TGAI - Inhalation Exposure Footnote 1 CITE ALL OWN 875.2800 TGAI – Descriptions of Human Activity Footnote 1

		\bigcirc			
Si	gnature /	V	1 ^		Date
	(SP		Carrie M. Tackema, Sr. Regulatory Manager	8-10-20

Ingredient: Lambda-cyhalothrin (PC Code 128897)





Date

Nufarm Limited

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX EPA Reg. No./File Symbol 35935-48 Page 14 of 15

4020 Aerial Center Parkway Morrisville, NC 27560

August 10, 2020

Product: Lambda-cyhalothrin Technical (NFA-0480001)

Ingredient: Lambda-cyhalothrin (PC Code 128897)

44353502 64977 PER 44353701 64977 PER 44353801 64977 PER 44351702 64977 PER 44358901 64977 PER 44388401 64977 PER 44396501 64977 PER 44396502 64977 PER 44396503 64977 PER 44396504 64977 PER 44374001 64977 PER 44375402 64977 PER 443754001 64977 PER 443754001 64977 PER 443754001 64977 PER 443754001 64977 PER 44374901 64977 PER 44374901 64977 PER 44374901 64977 PER	Guideline Reference Number	Series Name	MRID Number	Submitter (EPA CO#)	Status	Note
### Section	SERIES 875	OCCUPATIONAL AND RESIDENTIAL EXPOSURE TEST GUIDELINES				
44375402 64977 PER 44374901 64977 PER 44400101 64977 PER			41865602 41865603 41865604 42163801 42377801 42377802 42377803 42377805 42377806 42377807 42743301 44353001 44353201 4435301 44353701 44353701 44353701 44353701 44353701 44353701 44353701 44353701 44353701 44353701 44353701 44353701 44353701 44353701 44353701 44353701 44353701 44353701 44353701	64977 64977	PER R R R R R R R R R R R R R R R R R R	Footnote 1
			44375402 44374901	64977 64977	PER	

Signature

Name and Title: Carrie M. Tackema, Sr. Regulatory Manager **Date** 8-10-20





Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX						
Date August 10, 202	Date August 10, 2020 EPA Reg. No./File Symbol 35935-48 Page 15 of 15					
Nufarm Limited 4020 Aerial Center Parkway Morrisville, NC 27560 Product: Lambda-cyhalothrin Technical (NFA-0480001)						
Ingredient: Lambda-cyhalothrin (PC Code 128897)						

Guideline Reference Number	Series Name	MRID Number	Submitter (EPA CO#)	Status	Note
SERIES 875	OCCUPATIONAL AND RESIDENTIAL EXPOSURE TEST GUIDELINES				
875.2900	TGAI – Data Reporting and Calculations	44425001 46841701 47792701 47929401 47929402 47929403 47929404	64977 64977 64977 64977 64977 64977 64977	PER PER PER PER PER PER PER	
		47929405 48970201 49116901 49116902	64977 64977 64977 64977	PER PER PER PER	

FOOTNOTES

1. Nufarm is a member of the Spray Drift Task Force, Outdoor Residential Exposure Task Force, Agricultural Reentry Task Force, and Agricultural Handlers Exposure Task Force.

Signature

Name and Title:
Carrie M. Tackema, Sr. Regulatory Manager

8-10-20



Certification with Respect to Citation of Data					
Applicant's/Registrant's Name, Address and Telephone Number Nufarm Limited 4020 Aerial Center Parkway Morrisville, NC 27560				EPA Registration Number/ File Symbol 35935-48	
Active Ingredient(s) and/or represer		npound(s):		Date	
Lambda-cyhalothrin (PC code 128897)			August 10, 2020	
General use pattern(s) (list all those clair	ned for this prod	uct using		Product Name	
40 CFR Part 158)				Lambda-cyhalothrin Technical	
Terrestrial food/non-food; Aquatic food/non-food; nurseries, domestic of			ouse		
				red product labeled for all the same uses on s Exemption Statement (EPA Form 8570-27).	
I am responding to a Data Call-In compensation (the Data Matrix for				a list of companies sent offers of	
SECTION I: N	METHOD OF DA	ATA SUPPOR	T (Check	one method only)	
I am using the cite-all method of sup included with this form a list of comp offers of compensation (the Data Mashould be used for this purpose).	anies sent	under the	e selective d list of da	ective method of support (or cite-all option e method), and have included with this form a lata requirements (the Data Matrix form must	
	SECTION II: G	ENERAL OF	ER TO F	PAY	
requirements]	-	•		elective method to satisfy one or more data to the approval of this application, to the	
extent required by 1 in 10 t.	SECTION	I III: CERTIFIC	CATION		
submitted or cited in the application for regis under the selective method is indicated in Se properties or effects of this product or an ide is a type of data that would be required to be the application sought the initial registration of I certify that for each exclusive use that I have obtained the written permission of	istration, this form tration, the form for tration, the form for ection I, this applicantical or substantial submitted under to a product of ider study cited in sup f the original submits.	for reregistration, or reregistration, or reregistration, or ation is supporte ally similar produte data requirentical or similar or port of this regis attent to cite that s	n, or this Date or this Date down all date of the control of the c	or more of the ingredients in this product; and (2) fect on the date of approval of this application if	
the original data submitter; (b) I have obtained the written permission of the original data submitter to use this study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections $3(c)(1)(F)$ and/or $3(c)(2)(B)$ of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study. I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of					
their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA. I certify that the statements I have made on this form and all attachments to it are true, accurate and complete. I					
acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.					
Signature Date Typed or Printed Name and Title					
	August 10, 2	020	Carria	M Tackema Sr Regulatory Manager	

PRIA 3 – 21 Day Content Screen Review Worksheet (EPA/OPP Use Only) September 2012

21 Da	ay Screen Start Date:						
Expe	rts In-Processing Signature:ion management contacted on issues	Date		Fee P	aid: Ye	es	
Divis	ion management contacted on issues	NoYesL	Jate				
EPA F	Reg. Number:	EPA Receipt Date:					
	Items for		Yes	No	N/A*		
1	Application Form (EPA Form 8570-type	-1) signed & complete include	ling pacl	cage			
2	Confidential Statement of Formula dated (EPA Form 8570-4)	all boxes completed, form s	igned, a	nd			
2	a) All inerts, including fragrances, a	nnroved for the proposed	yes	no			
	uses (see Footnote A)	pproved for the proposed					
3	Certification with Respect to Citation completed and signed (N/A if 100% r	,	<u>)-34</u>)				
	Certificate and data matrix consistent						
	If applicant is relying on data that are to pay statement included. (see Footn	<u>=</u>	yes	no			
	If and live like the many letters of Angle		-1				
	If applicable, is there a letter of Author		_	1			
4	Formulator's Exemption Statement signed (N/A if source is unregistered	,		d			
	Data Matrix (EPA Form 8570-35) be completed and signed (N/A if 100% r		ies (<u>PR</u>	<u>98-5</u>)			
_			yes	no			
5	a) Selective Method (Fee category e	xperts use)					
	b) Cite-All (Fee category experts use	e)					
	c) Applicant owns all data (Fee cate	egory experts use)					
6	5 Copies of <u>Label</u> (<u>Electronic labels</u> available)	s on CD are encouraged and	d guida	nce is			
7	Is the data package consistent with	PR Notice 86-5					
8	Notice of Filing included with petit	tions_					

9	If applicable for conventional applications, <u>reduced risk rationale</u>						
	Required Data and/or data waivers. See Footnote C.						
	a) List study (or studies) not included with application						
10							
Comn	Comments:						
70.							
79							

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the <u>inert Web site</u> and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

- 1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
- 2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
- 3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
- 4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

- 1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

- 1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
- 3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

- B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.
- C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

					00011 65 11 1		
SEPA Env	United State		☐ Registra		OPP Identifier Number		
Env	ironmental Protec	•	y 🛛 Amendı	ment			
	Washington, DC	20460	☐ Other:				
	Applica	tion for Pe	sticide - Section	I			
1. Company/Product Number 35935-48		EPA Product Manager J. Herrick		3. Proposed Classification			
					None Restricted		
Name and Address of Applicant		6. Exp	edited Review. In	accordance	with FIFRA Section		
Nufarm Ltd.			3(c)(3) (b)(l), my product is similar or identical in composition				
4020 Aerial Center Parkwa Morrisville, NC 27560	y, Suite 101		beling to:		·		
Please send all corresponden	ce to "contact point"	" EPAR	Reg. No.:	_			
listed below	,	Produc	ct Name:				
		Section	on - II				
Amendment – Explain below			Final printed labe	els in response	to Agency letter dated		
Resubmission in response to	Agency letter dated		Me Too" Applica	tion			
Notification - Explain below.			Other - Explain b				
Explanation : Use addition	nal page(s) if necess	sary. (For Se	ection I and Section	II.)			
	Δnn	lication for	Amendment				
			- SEE ATTACH	JENT			
	I NIA CATEGO	JK1. K331	- SEL ATTACIT	AITI4 I			
CONTACT							
	1. Tackema						
<u>carrie.ta</u>	ckema@nufarm.cor	<u>n</u>					
Section - III							
Material This Product Will Be F	Packaged In:						
Child-Resistant Packaging	Unit Packaging		Water Soluble Pack	aging	2. Type of Container		
Yes*	☐ Yes		Yes		Metal		
⊠ No	⊠ No		⊠ No		Plastic		
	If "Yes"	No. per	If "Yes"	No. per	Glass		
*Certification must	Unit Packaging wgt.	container	Package wgt.	container	Paper		
be submitted			_		Other		
3. Location of Net Contents Infor		s) Retail Contain	ner	K 7	of Label Directions		
Label C	ontainer	RIII	RIIIK		On Label		
O. Managaria Mikish Labatis Affic	and the December 1				eling accompanying product		
Manner in Which Label is Affix	⊠ F	Lithograph Paper glued	☑ Other - cra	ack and peel			
Stenciled Section - IV							
Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application) Name Title Telephone No. (Include Area Code)							
Carrie M. Tackema Sr. Regulatory Manager 919-379-2528							
	Certification 6. Date Application						
I certify that the statements I have acknowledge that any knowingly under applicable law.							
2. Signature		3. Title Sr. Regulate	ory Manager				
4. Typed Name Carrie M. Tackema		4. Date					
Carrie IVI. Tackerila		August 10,	2020				

ATTACHMENT TO PRIA R351 SUBMISSION DATED 8-10-20 SECTION II EXPLANATION EPA REG. NO. 35935-48

 Nufarm Ltd. is submitting an application to amend Lambda-cyhalothrin Technical (EPA Reg. No. 35935-48) to add an alternate source of active ingredient identified by laboratory code (NFA-0480001). The alternate source (NFA-0480001) is identical or substantially similar in composition to the existing source(s).





4020 Aerial Center Parkway Morrisville, NC 27560 Phone: 919-379-2529

October 15, 2020

Document Processing Desk [6(a)(2)]
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Submitted via CDX PSP

Subject: 6(a)(2) Single Incidents Report Submission for EPA Company Number 35935 –

Nufarm Limited

Acute inhalation toxicity of Lambda-cyhalothrin in rats

To Whom It May Concern:

Enclosed is a single incident report for Nufarm Limited.

A copy of a study report, "Acute Inhalation Toxicity Test of Lambda-cyhalothrin Tecnico Agripec in Rats" was just received by the office of Nufarm Americas, Inc., in Morrisville, NC.

The results indicate significant toxic effects of Lambda-cyhalothrin in rats. It is unknown if the test substance is the same as Nufarm's Lambda-cyhalothrin Technical product, EPA Registration Number 35935-48.

A copy of the report is included with this submission.

If you have questions or need additional information, please do not hesitate to contact me by phone email at gordon.sargent@nufarm.com.

Sincerely,

Gordon Sargent Registration Manager



Nufarm

Morrisville, NC 27560 Phone: 919-379-2529

October 27, 2020

Document Processing Desk [6(a)(2)]
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Submitted via CDX PSP

Subject: 6(a)(2) Single Incidents Report Re-Submission for EPA Company Number

35935 – Nufarm Limited

MRID 51344001: Acute Inhalation Toxicity Test of LAMBDA CYHALOTHRIN

TECNICO AGRIPEC in Rats; 07/Feb/2007

To Whom It May Concern:

Enclosed is a single incident report for Nufarm Limited.

A copy of a study report, "Acute Inhalation Toxicity Test of Lambda-cyhalothrin Tecnico Agripec in Rats" which concluded in 2007, was only recently received by the office of Nufarm Americas, Inc., in Morrisville, NC. The results indicate significant toxic effects of Lambda-cyhalothrin in rats. It is unknown if the test substance is the same as Nufarm's Lambda-cyhalothrin Technical product, EPA Registration Number 35935-48.

A copy of the report is included with this submission.

I originally submitted the report on October 15, 2020 through the CDX Portal. However, EPA noted deficiencies in the submission including missing statement of confidentiality and GLP compliance pages; as well as a missing MRID number. All three deficiencies were rectified in this submission.

If you have questions or need additional information, please do not hesitate to contact me by phone or email at gordon.sargent@nufarm.com.

Sincerely.

Gordon Sargent Registration Manager



Via e-Submission

August 10, 2020

Ms. Jackie Herrick, PM#3 USEPA (7504P) Document Processing Desk (AMEND) Room S4900, One Potomac Yard 2777 S. Crystal Drive Arlington, VA 22202 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560 **nufarm.com**

RE: Application for Pesticide Registration - AMEND Lambda-cyhalothrin Technical, EPA Reg. No. 35935-48

Dear Ms. Herrick:

Nufarm Limited is submitting an application to amend Lambda-cyhalothrin Technical (EPA Reg. No. 35935-48) to add an alternate source of active ingredient identified by laboratory code (NFA-0480001). The alternate source (NFA-0480001) is identical or substantially similar in composition to the existing source(s). Nufarm has determined that this action falls under PRIA Category R351. We have prepaid the service fee for this action and provide the following records of payment:

Pay.gov Tracking ID: 26PLJVLQ Agency Tracking ID: 76023535030

In support of this e-Submission action, please find enclosed the data requirements listed in the table below, as well as the following:

- Application for Pesticide Registration (8570-1);
- Certification with Respect to Citation of Data (8570-34);
- Data Matrix- Agency & Public Use Copies (8570-35); and
- Proposed Confidential Statement of Formula (Alt CSF #1).

Vol. No.	Guideline Series	Study References	MRID No.
1	N/A	Administrative Documents	51192700
2	830-1550- 830.1900	Product Chemistry – Lambda-cyhalothrin Technical (NFA-0480001) Group A-Product Identity, Composition and Analysis; 11 pages (including a 420 page Confidential Attachment)	51192701
3	830.6302- 830.7950	Product Chemistry – Lambda-cyhalothrin Technical (NFA-0480001) Group B – Physical and Chemical Characteristics; 487 pages	51192702

If you should have any questions or concerns, please contact me at (919) 379-2528 or by email at carrie.tackema@nufarm.com.

Sincerely,

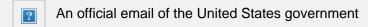
Carrie M. Tackema Sr. Regulatory Manager

Enclosure(s)

From: notification@pay.gov
To: Carrie Tackema

Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Date: Monday, August 10, 2020 10:18:38 AM



Pay.gov logo



Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees Pay.gov Tracking ID: 26PLJVLQ Agency Tracking ID: 76023535030

Transaction Type: Sale

Transaction Date: 08/10/2020 10:17:25 AM EDT Account Holder Name: Nufarm Americas Inc

Transaction Amount: \$13,888.00

Card Type: MasterCard

Card Number: ********7485

Registration Number: 35935-48 Company Name: Nufarm Limited

Company Number: 35935

Action Code: R351

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.



Pay.gov is a program of the U.S. Department of the Treasury, Bureau of the Fiscal Service

From: <u>Jackson, Tracy</u>
To: <u>Carrie Tackema</u>

Subject: RE: Submission Deficiency EPA Reg. No. 35935-48

Date: Thursday, August 27, 2020 7:41:24 AM

Attachments: <u>image001.png</u>

Hello Carrie,

Yes that is fine.

Thank You

Tracy Jackson
Contractor, US EPA
2777 S. Crystal Drive, S-4811
Arlington, VA 22202
jackson.tracy@epa.gov

From: Carrie Tackema < carrie.tackema@nufarm.com>

Sent: Thursday, August 27, 2020 7:35 AM **To:** Jackson, Tracy < Jackson. Tracy@epa.gov>

Subject: RE: Submission Deficiency EPA Reg. No. 35935-48

Hello Tracy,

The study has been corrected, however, it is a 487 page study and is confidential. Can it be sent back through CDX rather than over unsecure email?

Carrie Tackema

Sr. Regulatory Manager

T 919.379.2528 M 919.323.1368 carrie.tackema@nufarm.com

4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560 USA **nufarm.com**



From: Jackson, Tracy [mailto:Jackson.Tracy@epa.gov] **Sent:** Tuesday, August 25, 2020 9:20 AM **To:** Carrie Tackema < <u>carrie.tackema@nufarm.com</u>> Subject: Submission Deficiency EPA Reg. No. 35935-48 Dear Carrie Tackema, My name is Tracy Jackson and I am a contractor with the EPA. I am contacting you regarding your submission supporting the amended registration of Lambda-cyhalothrin Technical. (EPA Reg. Number: 35935-48). We have found a deficiency with the submission that will need to be addressed: Study 51192702 (Product Chemistry – Nufarm Lambda-Cyhalothrin Technical (NFA-0480001): Group B – Physical and Chemical Characteristics): Α. Your Statement of No Data Confidentiality Claims is contradicted by confidential markings on pages 36, 122, 142, 157, 180, 201 and 270. Please send a revised study with corrections to this e-mail address as soon as possible. If you have any questions, please do not hesitate to contact me. Thank You, Tracy Jackson Contractor, US EPA 2777 S. Crystal Drive, S-4811

Arlington, VA 22202 jackson.tracy@epa.gov

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

February 25, 2020

Carrie Tackema Senior Regulatory Manager Nufarm Ltd. 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560

Subject: Label Amendment – Adding uses to label (barley, buckwheat, cucurbit

vegetables, grass, forage, fodder, hay, oats, wild rice, rye, sorghum, and tuberous

and corm vegetables)

Product Name: Lambda-Cyhalothrin Technical

EPA Registration Number: 35935-48

Application Date: 10/10/2019 Decision Number: 556724

Dear Ms. Tackema:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Page 2 of 2 EPA Reg. No. 35935-48 Decision No. 556724

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Jamey Shuler at (703) 347-8036 or by email at Shuler.Jamey@epa.gov.

Id Herrick

Sincerely,

Jacquelyn Herrick, Product Manager 03 Invertebrate & Vertebrate Branch 1 Registration Division (7505P) Office of Pesticide Programs

Enclosure

Lambda-cyhalothrin **Technical**

ACCEPTED

02/25/2020

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 35935-48

ACTIVE INGREDIENT:

Lambda-cyhalothrin......95.0% OTHER INGREDIENTS:5.0%

KEEP OUT OF REACH OF CHILDREN **DANGER / PELIGRO**



Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

For Chemical Spill, Leak, Fire, or Exposure, Call CHEMTREC (800) 424-9300 For Medical Emergencies Only, Call (877) 325-1840

> Manufactured for **NUFARM LIMITED** 4020 Aerial Center Parkway Morrisville, NC 27560



EPA REG. NO. 35935-48 EPA EST. NO.

NET WEIGHT: Lbs. Kg)

035935-00048.20200225.amend

FIRST AID				
IF SWALLOWED	 Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person. 			
IF ON SKIN OR CLOTHING	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 to 20 minutes. Call a poison control center or doctor for treatment advice. 			
IF IN EYES	 Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. 			
IF INHALED	 Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice. 			

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-877-325-1840 for emergency medical treatment information.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS DANGER / PELIGRO

Fatal if swallowed. May be fatal if absorbed through skin or inhaled. Causes substantial but temporary eye injury. Do not get in eyes, on skin or on clothing. Wear protective clothing, including long sleeved shirt and long pants, socks, shoes, goggles or full face shield and rubber gloves. Do not breathe vapors. Wear a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any R, P, or HE prefilter. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco products, or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish and other aquatic organisms. Keep out of lakes, streams, or ponds. Do not discharge effluent containing this product directly into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

PHYSICAL AND CHEMICAL HAZARDS

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This product is for manufacturing use only and is intended for formulation into end use products for:

TERRESTRIAL NONFOOD: Non-croplands (excluding public land), Tobacco (burley and flue-cured).

TERRESTRIAL AND AQUATIC FOOD: Alfalfa, Barley, *Brassica* (head and stem), Buckwheat, Canola, Corn (field, pop, seed and sweet), Cotton, Cucurbit Vegetables, Fruiting Vegetables, Garlic, Grass, Forage, Fodder, and Hay, Legume Vegetables, Lettuce (head and leaf), Oats, Onion (dry bulb), Peanuts, Pome Fruits, Rice, Wild Rice, Rye, Sorghum, Stone Fruit, Sugarcane, Sunflower, Tree Nuts, Triticale, Tuberous and Corm Vegetables, and Wheat.

FORESTRY: Confer and Deciduous trees (plantations, nurseries and seed orchards)

DOMESTIC INDOOR AND OUTDOOR

NON-DOMESTIC INDOOR AND OUTDOOR

GREENHOUSE NON-FOOD CROP AND NURSERIES

All other uses for which the USEPA has accepted the required date and/or citations of data that the formulator has submitted in support of registration. Uses for experimental purposes that are in compliance with EPA requirements.

Formulators using the product are responsible for obtaining EPA registration for their formulated product.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Keep container closed when not in use. Store in original container and out of the reach of children, preferably in a locked storage area.

Handle and open container in a manner as to prevent spillage. If the container is leaking or material is spilled for any reason or cause, carefully sweep material into a pile and dispose of as directed for pesticides below.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional office for guidance.

CONTAINER HANDLING:

Nonrefillable container. Do not reuse or refill this container. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into manufacturing equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into manufacturing equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Pressure rinse as follows: Empty the remaining contents into manufacturing equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over manufacturing equipment or mix tank or collect rinsate for later use or disposal. Insert pressure-rinsing nozzle in the side of the container, and rinse at about 40 psi for at least 30 seconds. Drain for 10 seconds after the flow begins to drip. Then offer for recycling if available, or puncture and dispose of in a sanitary landfill or by other procedures approved by State and local authorities.

WARRANTY DISCLAIMER

The directions for use of this product must be followed carefully. To the extent consistent with applicable law, (1) the goods delivered to you are furnished "As is" by manufacturer or seller and (2) manufacturer and seller make no warranties, guarantees, or representations of any kind to buyer or user, either express or implied, or by usage of trade, statutory or otherwise, with regard to the product sold, including, but not limited to merchantability, fitness for a particular purpose, use, or eligibility of the product for any particular trade usage. Unintended consequences, including but not limited to ineffectiveness, may result because of such factors as the presence or absence of other materials used in combination with the goods, or the manner of use or application, including weather, all of which are beyond the control of manufacturer or seller and assumed by buyer or user. This writing contains all of the representations and agreements between buyer, manufacturer and seller, and no person or agent of manufacturer or seller has any authority to make any representation or warranty or agreement relating in any way to these goods.

LIMITATION OF LIABILITY

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, IN NO EVENT SHALL MANUFACTURER OR SELLER BE LIABLE FOR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, OR FOR DAMAGES IN THEIR NATURE OF PENALTIES RELATING TO THE GOODS SOLD, INCLUDING USE, APPLICATION, HANDLING, AND DISPOSAL TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, MANUFACTURER OR SELLER SHALL NOT BE LIABLE TO BUYER OR USER BY WAY OF INDEMNIFICATION TO BUYER OR TO CUSTOMERS OF BUYER, IF ANY, OR FOR ANY DAMAGES OR SUMS OF MONEY, CLAIMS OR DEMANDS WHATSOEVER, RESULTING FROM OR BY REASON OF, OR RISING OUT OF THE MISUSE, OR FAILURE TO FOLLOW LABEL WARNINGS OR INSTRUCTIONS FOR USE, OF THE GOODS SOLD BY MANUFACTURER OR SELLER TO BUYER. ALL SUCH RISKS SHALL BE ASSUMED BY THE BUYER, USER, OR ITS CUSTOMERS. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BUYER'S OR USER'S EXCLUSIVE REMEDY, AND MANUFACTURER'S OR SELLER'S TOTAL LIABILITY SHALL BE FOR DAMAGES NOT EXCEEDING THE COST OF THE PRODUCT.

If you do not agree with or do not accept any of directions for use, the warranty disclaimers, or limitations on liability, do not use the product, and return it unopened to the Seller, and the purchase price will be refunded.

(RV[mmddyy])